



S/N 09/125,953

**RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1655**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: FOSTAD ET AL. Examiner: B. SISSON
Serial No.: 09/125,953 Group Art Unit: 1655
Filed: December 10, 1998 Docket No.: 7885.56USWO
Title: IMMUNO-MAGNETIC CELL SEPARATION USED IN
IDENTIFICATION OF GENES ASSOCIATED WITH SITE-
PREFERENCED CANCER METHASTASIS FORMATION

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on ~~July 20~~ ^{July 20}, 2000.


John F. Gressens

AMENDMENT UNDER 37 C.F.R. § 1.116

BOX AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants provide the following amendment and remarks in response to the Office
Action mailed April 21, 2000. Reconsideration and re-examination in light of the amendment
and remarks presented below is respectfully requested.



AMENDMENT

In the Claims

Please delete claims 10 and 11.

REMARKS

Claims 10 and 11 have been canceled. Claims 1-9 remain pending in this application.

Lack of Enablement Rejection

Claims 10 and 11 have been rejected under 35 U.S.C. 112, first paragraph, because the claimed subject matter allegedly was not described in the specification in such a way to enable one of skill in the art to make and/or use the invention. Claims 10 and 11 have been canceled rendering the rejection moot. Withdrawal of the rejection is respectfully requested.

Anticipation Rejection

Claims 1-9 have been rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Høifødt et al. (WO 95/24648). Applicants respectfully traverse this rejection.

Høifødt et al. do not teach or disclose the presently claimed invention. As stated in the March 6, 2000 Response to the Examiner's December 6, 1999 Official Action, Høifødt et al. do not disclose gene cloning to study differences in mRNA expression levels by comparison.

The above argument was deemed unpersuasive because, according to the Examiner, Høifødt et al. disclose establishing a clonal colony at page 7 and disclose "a variety of non-limiting methods used in the analysis of nucleic acid sequences where the cells from which nucleic acid is obtained are first isolated" at pages 7-8.

First, referring to page 7 of the reference, there is no mention of establishing a clonal colony. The reference describes growing a group of cells remaining on the filter. Cloning of cells means picking out and growing single cells. The isolation of cells in order to obtain up to 100% specific target cells as required by the claimed invention is neither mentioned nor contemplated in the reference. A study, whereby a comparison of mRNA expression levels between cell populations, could not be performed according to the method of Høifødt et al. because it was not possible to enrich the target cells such that contaminating material was avoided. In addition, gene cloning, which is also required by the claimed invention, is notably not mentioned or disclosed by the reference.

Second, at line 32, page 7 of the reference, it is mentioned that it would be "...of interest to examine specific genes in a pure population of target cells ...". However, the specific genes referred to here are previously known genes or their expression in a group of cells. The presently claimed invention regards detection of unknown genes by comparing gene expression in cells isolated from different locations.

Unlike the claimed invention, the method of Høifødt et al. would not have been expected to produce samples of cells, for example from solid primary tumors and their respective metastatic tumors, representative enough to perform a comparison of the expression of unknown genes in the cells.

Withdrawal of the method is respectfully requested.

CONCLUSION

Applicants respectfully assert that the instant claims are in a condition for allowance, and earnestly solicit a notice to that effect.

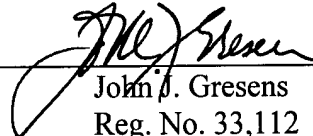
If the Examiner has any questions regarding the foregoing, it is respectfully requested that he call the undersigned.

Respectfully submitted,

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July 20, 2000

Date



John J. Gresens
Reg. No. 33,112
JJG/KMC

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